UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.* JULIE LONG, *Plaintiffs*, v. JANSSEN BIOTECH, INC., *Defendant.*	Civil Action No. 16-CV-12182-FDS

DEFENDANT'S REPLY IN SUPPORT OF ITS MOTION FOR JUDGMENT ON THE PLEADINGS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

INTRODUCTION

In its Memorandum of Law in Support of Its Motion for Judgment on the Pleadings, Defendant Janssen Biotech, Inc. ("Janssen") documented how three prior federal litigations—*In re Average Wholesale Price Litigation* ("*AWP*"), *In re Heineman*, and *In re Greer*—alleged or otherwise disclosed that Janssen and its predecessor Centocor offered education to physicians on how to set up and operate an in-office infusion ("IOI") practice for Remicade.

Relator acknowledges that her "core" allegation is indeed that Janssen offered education to physicians about IOI of Remicade and its successor drug Simponi ARIA, Opp'n 4, and that this supposed "scheme" was in operation at the time of *AWP*, *Heineman*, and *Greer*, *id.* at 2, 14. Nevertheless, Relator argues that the public disclosure bar does not apply. In doing so, she baselessly asserts that Janssen "distorts" the prior public disclosures (which Janssen's judicially noticeable exhibits confirm Janssen described and quoted entirely accurately) and makes a series of arguments that ignore and are directly contrary to established precedent.

For the reasons below, none of Relator's arguments that the public disclosure bar does not preclude her later-filed suit is successful.

ARGUMENT

I. *Winkelman* Step One: The Essential Elements of Relator's Allegations Were Publicly Disclosed in *AWP*, *Heineman*, and *Greer*.

The public disclosures in *AWP*, *Heineman*, and *Greer* satisfy the first step of the *Winkelman* analysis because they disclosed "the essential elements" of Relator's alleged fraud. *Winkelman*, 827 F.3d 201, 208 (1st Cir. 2016). Relator's arguments to the contrary are meritless.[1]

[1] To the extent Relator suggests that *AWP*, *Heineman*, and *Greer* did not disclose the alleged fraud because those disclosures occurred across three separate litigations or within the extensive filings in the *AWP* multi-district litigation, that argument is meritless. *See* Opp'n 13. The "set[] of facts" publicly disclosing an alleged fraud "may originate in different sources, as long as they 'lead to a

First, Relator seeks to discount the disclosures in *AWP*, *Heineman*, and *Greer* by noting that those cases centered on allegations of "marketing the spread" that physicians could earn on IOI of Remicade. Opp'n 11–13. That argument is a red herring. Janssen does not contend that allegations about marketing the spread disclose Relator's allegations. Janssen instead contends that, as documented in the Memorandum, various disclosures in *AWP*, *Heineman*, and *Greer* went beyond mere allegations of marketing the spread, and directly addressed Centocor's efforts to educate physicians about IOI of Remicade. *See* Mem. at 19–22.

Second, and relatedly, Relator suggests that the disclosures in *AWP*, *Heineman*, and *Greer* should not count because they did not describe the provision of IOI education as being fraudulent. Opp'n 15. That is flatly incorrect with respect to *Heineman* and *Greer*, which claimed that the alleged conduct constituted fraud under the FCA. *Heineman* Compl., Ex. N, ¶¶ 50, 45, 35; *Greer* Compl., Ex. O, ¶¶ 54, 93. And if the IOI education Janssen offered to physicians really were kickbacks, as Relator alleges, then that fraudulent conduct was apparent on the face of the disclosures in *AWP*. In any event, "the public disclosure bar contains no requirement that a public disclosure use magic words or specifically label disclosed conduct as fraudulent." *Winkelman*, 827 F.3d at 209. This is because "[a] relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed." *Id.* (quotation marks omitted) (quoting *U.S. ex rel. Findley v. FPC-Boron Emps.' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997)).[2]

---

plausible inference of fraud' when combined." *Winkelman*, 827 F.3d at 208 (quoting *U.S. ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54 (1st Cir. 2009)).

[2] Relator's reliance on *U.S. ex rel. Clarke v. Aegerion Pharm., Inc.*, No. 13-cv-11785, 2019 WL 1437914 (D. Mass. Mar. 31, 2019), is misplaced. That case held that a company's public "inflated estimate[s]" did not trigger the public disclosure bar because they "d[id] not by themselves constitute the false claims alleged," but were only "essential background information" for

Third, Relator contends that the public disclosures in *AWP*, *Heineman*, and *Greer* were "outdated," and that there were "no allegations that indicated that the practices alleged in those cases would continue." Opp'n 22–23. This argument also fails. Relator openly admits that the conduct she alleges to be fraudulent was underway at the time of *AWP*, *Heineman*, and *Greer*.[3] And given that Janssen's predecessor company Centocor publicly disclosed in the *AWP* litigation that it was providing education to physicians in an effort to increase IOI of Remicade, *see, e.g.*, Hoffman Dep., Ex. B, at 13–14; McHugh Decl., Ex. J, at 10,[4] "there was every reason to think that" Janssen's alleged "scheme would remain velivolent." *Winkelman*, 827 F.3d at 212.[5]

Relator's cited authorities are inapposite. Opp'n 23 (citing *U.S. ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34, 45 (D. Mass. 2014); *Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 353 (S.D.N.Y. 2014)). Both cases concerned allegations of fraud that occurred *post-settlement* of prior FCA claims, when the Government was unaware that the fraud was still ongoing. *Booker*, 9 F. Supp. at 46 (relator's allegations were "new fraudulent activity"); *Kester*, 43 F. Supp. 3d at 352–53 (no public disclosures revealed "intention not to comply" with settlement). Neither case is applicable to Relator's allegations of continuous fraud dating back to the time of *AWP*, *Heineman*, and *Greer*. Indeed, *Booker* expressly recognized that an action like Relator's that "covers only 'somewhat different time periods'" for a single "scheme" has "little value." 9 F. Supp. 3d at 45

Relator's claims. *Id.* at *8. Here, *AWP*, *Heineman*, and *Greer* disclosed that Janssen was offering IOI education to physicians—the very conduct alleged to be fraudulent in this case.

[3] *See, e.g.*, Opp'n 14 ("At the time of the *AWP Class Action* trial, the fraud Relator alleges was in its early infancy."); Second Amended Complaint, ECF No. 55, ¶ 118 ("From at least 2003 through 2016, Janssen engaged in the illegal kickback scheme detailed below to expand the IOI market and grow sales of Remicade and Simponi ARIA within the IOI market.").

[4] All Exhibit pincites refer to ECF pagination.

[5] Moreover, Relator overstates the temporal gap between her action and the prior federal litigations publicly disclosing her alleged fraud. For instance, the Government declined intervention in *Heineman* and *Greer* in May 2010, only six years before the present action was filed.

(first quoting *U.S. ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 505, 517 (6th Cir. 2009), *abrogated on other grounds by U.S. ex rel. Rahimi v. Rite Aid Corp.*, 3 F.4th 813 (6th Cir. 2021), then quoting *U.S. ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 3d 8, 13 (D.D.C. 2003)).

Fourth, while acknowledging that various disclosures in *AWP*, *Heineman*, and *Greer* "may be relevant to [her] allegations," Opp'n 17; *see also id.* at 11, Relator nevertheless accuses Janssen of mischaracterizing the content and relevance of a number of particular disclosures. In reality, Janssen provided a completely accurate description of the public disclosures at issue. Relator's Exhibit 2 to its Opposition does not undermine that; in fact, it confirms it.[6]

For example, Relator characterizes Centocor's Office-Based Infusion Guide as a mere "document discussing the profitability of Remicade." Opp'n 16. That is demonstrably false. The Guide's stated "purpose" was "to provide physicians, office managers and clinical staff members a better understanding of the key practical issues surrounding the administration of REMICADE™ in the office setting." Pl.'s Ex. 252, Ex. I, at 5. The Guide thus provides those "considering providing REMICADE™ infusions in office" with "a comprehensive list of important considerations, including," but not limited to, "an analysis of financial implications and an evaluation of practice resources." *Id.*; *see also AWP* Trial Tr., Ex. G, at 4 (Centocor testimony stating that "[f]inances were a part of it, but as you can see as you go through the [Office-Based Infusion] guide, there are many other logistical instructions as well as practical considerations that they had to evaluate."). Over the course of 23 pages, the Guide does just that. The Guide includes a "REMICADE™ (infliximab) Appropriateness Worksheet," which assists practices in determining whether they are "a good candidate for REMICADE™ therapy." Pl.'s Ex. 252, Ex. I, at 6. The Guide also advises on "Resource Evaluation," "Space Requirements," and

[6] Relator did not request nor receive consent or leave to file its argumentative 14-page Exhibit 2.

"Administration Supplies" detailing both "Essential" components of an IOI suite (*e.g.*, "Standard examination room table or chair," "non-PVC IV bag or glass bottle of 0.9% sodium chloride") and "Optional" components (*e.g.*, "Magazines/reading material," "TV/VCR,"). *Id.* at 11–14. It further describes required "Staff Training & Certification" (*e.g.*, "certification for inserting intravenous catheters and administering IV therapies"); tips for "Resource Optimization" (*e.g.*, administer "infusions on a dedicated day in order to maximize efficiency"); and "Patient Comfort" recommendations (*e.g.*, "Companion/family member seating," "Drinking & eating," "Entertainment"). *Id.* at 15–16. It also includes "Practical Examples" of real-world IOI practices, including details about different set-up scenarios for IOI practices (*e.g.*, single site practices, multi-site practices, and multi-specialty practices). *Id.* at 4, 17–20. In short, it is Relator's offhand dismissal of the Guide as a "document discussing the profitability of Remicade," Opp'n 16, not Janssen's citation of it as a public disclosure, that is misleading.

Just as egregiously, Relator argues without support that disclosures from *AWP*, *Heineman*, and *Greer* that directly disclose Relator's allegations on their face are actually limited somehow to "marketing the spread." *See, e.g.*, Opp'n 14–15. For instance, Relator mischaracterizes the *AWP* Court's finding that "Centocor developed and implemented a Practice Management Program ('PMP') to educate physicians on buying, infusing, and billing for Remicade," *AWP* Order, Ex. L, at 13, as solely concerning "tactics Centocor employed to market Remicade's spread to doctors," Opp'n 14–15. But that is simply not a plausible reading of the Court's language, particularly given the broader context of that finding—including a Centocor witness at the *AWP* trial (Dr. John Hoffman) who testified in a deposition that the company's "practice management program" was designed "to provide education and tools to physicians to help them not only get over some of those disincentives and obstacles that they had, but also to be able to deliver those infusions in a

more effective and efficient manner on an ongoing basis." Ex. B, at 11–12; *see also id.* (Practice Management Program intended to "mak[e] sure that . . . all of the things associated with" IOI were addressed). Strikingly, Relator *never discusses* Dr. Hoffman's deposition testimony. Relator's failure to address this direct public disclosure that Centocor was educating physicians on both setting up and operating an IOI practice *"on an ongoing basis"*—on top of her repeated mischaracterizations of other disclosures revealing the same—is fatal to her argument that the essential elements of her alleged fraud have not been publicly disclosed. *Id.* at 12.

Fifth, and finally, Relator suggests that *AWP*, *Heineman*, and *Greer* did not disclose the "essential elements" of the fraud she alleges because the disclosures in those cases would not be enough, standing alone, to state a claim under the FCA. Opp'n 15. This argument has a false premise. *Winkelman*'s "essential elements" test does not require disclosure of every legal element of a fraud claim, sufficient to satisfy Rule 9(b). To the contrary, *Winkelman* requires only that public disclosures are sufficient to "lead to a plausible inference of fraud" or "put the government on notice of the potential fraud." 827 F.3d at 208–09 (quoting *Ondis*, 587 F.3d at 54). Because the disclosures in *AWP*, *Heineman*, and *Greer* were more than sufficient to give rise to an inference of the fraud Relator alleges—*i.e.*, that Janssen provided free education to physicians about setting up and operating an IOI practice, that such education could have substantial independent value for physicians administering other infusible medications, and that those physicians submitted claims to Medicare—the essential elements of Relator's alleged fraud have been publicly disclosed.[7]

[7] Relator asserts that "Janssen never mentioned or produced" certain documents from the *AWP* litigation during discovery in this case. Opp'n 18. Discovery is ongoing and Janssen has produced millions of pages of documents, including more than 25,000 pages originally produced to the Department of Justice in connection with its investigation in response to the *Heineman* complaint beginning in 2003. In any event, Relator's discovery-related arguments are irrelevant to the question of whether her allegations were publicly disclosed in *AWP*, *Heineman*, and *Greer*.

II. *Winkelman* Step Two: *AWP, Heineman*, and *Greer* Are All Statutorily Qualifying Public Disclosures.

Relator next argues that the *AWP*, *Heineman*, and *Greer* litigations were not federal civil hearings "in which the Government or its agent [was] a party," and thus that the public disclosures made in those litigations do not bar her later-filed suit. Opp'n 6, 9–10 (quoting 31 U.S.C. § 3730(e)(4)(A)). This argument goes against the overwhelming weight of authority, which confirms that *AWP*, *Heineman*, and *Greer* all qualify for purposes of the public disclosure bar.

a. *AWP* Is a Statutorily Qualifying Public Disclosure.

Relator's argument that the *AWP* litigation was not a federal civil hearing to which the government was a party fails to acknowledge, much less distinguish, the two decisions expressly holding to the contrary. *See United States v. CSL Behring, LLC*, 158 F. Supp. 3d 782, 787–89 (E.D. Mo. 2016), *aff'd* 855 F.3d 935 (8th Cir. 2017) (identifying the *AWP* litigation as a "disclosure made in [a] qualifying source[]"); *United States v. CSL Behring, LLC*, 855 F.3d at 944–945 (affirming that the *AWP* litigation constitutes a "disclosure made in [a] qualifying source[]").

Those courts got it right: The United States was listed on the docket for the *AWP* multi-district litigation as an Interested Party, and thus received notice of filings in that litigation. Docket Report, *AWP*, 01-cv-12257. Furthermore, the Government *actually participated* in the *AWP* multi-district litigation, both by making two filings itself, and by filing a notice consenting to the transfer of a *qui tam* into the multi-district litigation.[8]

[8] *See* Notice of Transfer, *AWP*, 892 F. Supp. 2d 341 (D. Mass. 2009) (No. 01-cv-12257), ECF No. 2924 ("As a new party to this action, the United States" is available for "a status conference before this Court in MDL Docket No. 1456.") (No. 01-cv-12257); Brief of the United States as Amicus Curiae, *AWP*, 892 F. Supp. 2d 341 (D. Mass. 2006) (No. 01-cv-12257), ECF No. 3104; Supplemental Brief of United States on the Federal Upper Limit, *AWP*, 892 F. Supp. 2d 341 (D. Mass. 2009) (No. 01-cv-12257), ECF No. 6693; Docket Report, *AWP*, 01-cv-12257.

It would elevate form over substance to conclude that the Government was nevertheless not the relevant *type* of "party" to *AWP* for purposes of triggering the public disclosure bar. The "ultimate inquiry" of the public disclosure bar is "whether the government has received fair notice, prior to the suit, about the potential existence of the fraud." *Winkelman*, 827 F.3d at 208–09. Holding that the Government is not a "party" to litigation in which it participated and received notice of filings would undermine both the text of the FCA (which does not specify what kind of party the Government must be to trigger the public disclosure bar) and its clear purpose.[9] Relator offers no compelling reason for this Court to depart from the rule of *Behring*.[10]

b. *Heineman* and *Greer* Are Statutorily Qualifying Public Disclosures.

Relator also argues against authority in asserting that *Heineman* and *Greer* were not suits "in which the Government *or its agent* [was] a party." 31 U.S.C. § 3730(e)(4)(A)(i) (emphasis added). According to Relator, the *Heineman* and *Greer* relators were not Government agents, because the Government declined to intervene in those cases. Opp'n 9–10. Relator is mistaken.

Relator bases her argument almost entirely around *Medtronic*, a single outlier district court decision holding that an FCA relator—who brings claims *on behalf* of the United States, the real

[9] Courts have interpreted the statutory term "party" broadly to include interested non-parties where doing otherwise would thwart the statute's purpose. *See, e.g.*, *Breyer v. Rockwell Int'l Corp.*, 40 F.3d 1119, 1125 n.7 (10th Cir. 1994) ("[W]e do not read the word 'party' so literally as to mean 'named party to an action,'" where doing so "would effectively emasculate" the provision); *Burns v. Grupo Mexico S.A. De. C.V.*, No. 07 Civ. 3496, 2007 WL 4046762, at *3–4 (S.D.N.Y. Nov. 16, 2007) ("[N]umerous courts" have allowed removal by non-parties under removal statute allowing a "party" to "remove any claim or cause of action[.]"); *In re Bellucci*, 9 B.R. 887, 889 (Bankr. D. Mass. 1981) ("It matters not that the trustee was not a party in the state court suit, since it is clear that as that suit might affect the property of the estate, he is a party in interest.").

[10] Relator's citation to *U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 931 (2009), is wholly inapposite. *See* Opp'n 9. *Eisenstein* concerned the distinct question of whether the United States is a "party" to an action for purposes of an appeal filing deadline under Federal Rule of Appellate Procedure 4(a)(1)(B). 556 U.S. at 931. That context is irrelevant here because the focus of the public disclosure bar is whether the Government was on notice of Relator's allegations, not whether the Government is a party for purposes of the timing of filing an appeal. *Id.* at 931–33.

party in interest in a *qui tam* suit—only qualifies as the Government's agent if the Government chooses to intervene. *Id.* (citing *U.S. ex rel. Forney v. Medtronic, Inc.*, 327 F. Supp. 3d 831 (E.D. Pa. 2018)). That highly counterintuitive ruling has been rejected by courts across the country, which have held that a relator is *always* the Government's agent in a *qui tam* suit under the FCA.[11]

The majority view is the correct one. A *qui tam* relator is the Government's agent. *See, e.g., Holloway,* 960 F.3d at 845–46 ("Who, if not the private relator, is the government's agent?"). And Courts have correctly recognized that a relator continues to be the Government's agent even if the Government declines intervention because, even in a declined case, the relator still "pusu[es] the action on the Government's behalf," and the Government always remains the real party in interest. *Gilbert*, 305 F. Supp. 3d at 1324; *see also, e.g., Eisenstein*, 556 U.S. at 930 (the Government remains the "real party in interest" in declined FCA suit).[12]

Relator's theory that declining intervention somehow transforms the Relator's relationship with the Government into one of non-agency is further refuted by the Government's significant ongoing control even in declined cases. The Government "still receives copies of all pleadings and deposition transcripts, can move to stay discovery if it interferes with ongoing criminal or civil investigation, [] has the right to approve or reject a stipulated dismissal," and can intervene later with good cause. *Holloway*, 960 F.3d at 845 (quotation marks omitted); *see also Riley v. St. Luke's*

[11] *See, e.g., U.S. ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836, 845–46 (6th Cir. 2020) ("[R]elator is, in all cases the government's agent under § 3730(e)(4)(A)(i)," and "[a] majority of courts have rejected [*Medtronic*'s] reasoning."); *U.S. ex rel. Gilbert v. Va. Coll. LLC*, 305 F. Supp. 3d 1315, 1321–25 (N.D. Ala. 2018) ("[*Q*]*ui tam* relators are 'agents' of the Government under the most reasonable reading of § 3730(e)(4)(A)(i)."); *United States v. Allstate Ins. Co.*, No. 19-cv-11615, 2022 WL 3213529, at *9–10 (E.D. Mich. Aug. 9, 2022) ("The Court agrees with '[a] majority of courts' that relators in a *qui tam* case are considered 'agent[s]' under § 3730(e)(4)(A)(i) when the Government declines to intervene").

[12] Relator's own filings recognize that an FCA suit is brought on behalf of the United States, even post-declination. *See, e.g.*, Relator's Mem. of Law in Opposition to Def.'s Mot. for Judgment on the Pleadings, ECF No. 381, at 6 ("Relator pursues this action on behalf of the United States[.]").

Episcopal Hosp., 252 F.3d 749, 753 (5th Cir. 2001) ("[E]ven in cases where the government does not intervene, there are a number of control mechanisms present in the *qui tam* provisions[.]"). Furthermore, the purpose of the public disclosure bar—*i.e.*, barring suits in which the Government "has received fair notice, prior to the suit, about the potential existence of the fraud," *Winkelman*, 827 F.3d at 208–09—is far better served by the majority rule. Because the Government continues to receive copies of case filings, *see Holloway*, 960 F.3d at 845, the fair-notice purpose of the public disclosure bar remains satisfied even in declined cases.

Borrowing an argument from *Medtronic*, Relator nevertheless insists that the Supreme Court in *Vermont Agency of Natural Resources v. U.S. ex rel. Stevens*, 529 U.S. 765 (2000), has already "rejected the argument that a relator is a statutorily designated agent of the Government." Opp'n 10. Relator misreads *Vermont Agency*. That case was concerned with identifying the basis for a *qui tam* relator's Article III standing "*[f]or the portion of the recovery retained by the relator*" in an FCA suit. 529 U.S. at 771–74 (emphasis added). *Vermont Agency* merely recognized that, for that portion of the recovery, "some explanation of standing other than agency for the Government must be identified." *Id.* (emphasis added). As the majority of courts have recognized, *see supra*, at 9, *Vermont Agency* does not support the proposition that a relator is not the Government's agent in a declined case for purposes of the public disclosure bar.

III. *Winkelman* Step Three: Relator's Allegations Are Substantially Similar to the Public Disclosures in *AWP, Heineman*, and *Greer*.

The statutorily qualifying public disclosures in *AWP*, *Heineman*, and *Greer* are also "substantially similar" to Relator's allegations, because those disclosures "revealed" "the anatomy of th[e] scheme" alleged by Relator. *Winkelman*, 827 F.3d at 210.

Relator acknowledges that the scheme she alleges dates back to the *AWP*, *Heineman*, and *Greer* litigations, although she contends that the scheme has "evolved and expanded" since then.

Opp'n 13. As "courts have consistently found," however, "a continuing fraud in a new time period is not a new fraud, but is, instead, substantially similar to prior public disclosures." *U.S. v. Medco Health Sols., Inc.*, No. 11-684, 2017 WL 63006, at *8 (D. Del. Jan. 5, 2017) (collecting cases); *see also, e.g., U.S. ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134, 144 (1st Cir. 2020) (finding substantial similarity where relator alleged a previously disclosed scheme operated for "a longer period of time," implicated a different kind of "remuneration," applied to additional "drugs," and utilized "different and more aggressive methods." (quotation marks omitted)).

In arguing that her allegations are not substantially similar to *AWP*, *Heineman*, and *Greer*, Relator relies almost entirely on her earlier argument that the "essential elements" of the fraud she alleges were not publicly disclosed in those cases. *See* Opp. 23–24 ("As explained above, the asserted public disclosures do not allege the essential elements of the fraud Relator alleges, much less suggest that Janssen was engaging in this conduct."). But as discussed, *supra*, at 1–6, Relator is wrong that *AWP*, *Heineman*, and *Greer* did not disclose the "essential elements" of her alleged fraud. For those same reasons, her allegations are also substantially similar to those disclosures.

IV. Relator Does Not Qualify as an Original Source.

Because her allegations have been publicly disclosed, Relator can only pursue this suit if the "new information" she adds "is sufficiently significant or essential as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures." *Winkelman*, 827 F.3d at 211. Information is material only if it is sufficiently important to "affect" the Government's "decision-making." *Id.* Here, public disclosures indicated that Janssen provided IOI education to doctors (including doctors who billed government healthcare programs). *If* that education constituted kickbacks, those disclosures were more than sufficient to determine that there was a potential "fraud" on the Government. Relator fails to carry her burden to show that any of the ten supposedly "material additions" ("MAs") she identifies in

her Opposition are material in light of existing disclosures. *See U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 118, F. Supp. 3d 412, 423−24 (D. Mass. 2015), *aff'd*, 827 F.3d 201 (1st Cir. 2016) ("Plaintiff-relators bear the burden of proving that they are original sources").

Several of Relator's purported additions merely add detail to conduct that has plainly already been disclosed. *See* Opp'n 26 (MA-2: "[s]pecific and detailed information concerning the IOI Support that constitute[s] the illegal remuneration"); *id.* at 28 (MA-7: "[s]pecific information linking Janssen's provision of the illegal remuneration to the subsequent submission of false claims to Medicare"). The law is clear, however, that "[o]ffering specific examples of" alleged "conduct" or "add[ing] detail or color to previously disclosed elements of an alleged scheme" is immaterial. *Winkelman*, 827 F.3d at 212–13.

Other of Relator's purported additions are immaterial in light of existing disclosures. For instance, Relator argues that she adds "[s]pecific and detailed information regarding the services' . . . substantial value beyond Remicade and Simponi ARIA," Opp'n 26 (MA-4), pointing to this Court's discussion of her allegation that IOI education for Remicade could be "applied equally to other infusible drugs," producing a valuable "spillover effect." *Id.* (citing Order, ECF No. 75, at 9, 18). But given Janssen's disclosure that it was educating physicians on how to, *e.g.*, more effectively schedule, staff, and set-up IOI suites, *see* Mem. 21–23, it is not "material" for Relator to point out that some physicians might use their offices to also infuse other medications. *See U.S. ex rel. Paulos v. Stryker Corp*., No. 11-0041, 2013 WL 2666346, at *8 (W.D. Mo. June, 12, 2013), *aff'd* 762 F.3d 688 (8th Cir. 2014) (relator not an original source where her "claims are simply the logical and obvious consequence of information that was already publicly disclosed[.]").

Similarly, Relator's allegation that "one of Janssen's main purposes" in providing IOI education to physicians "was to induce doctors to prescribe and infuse Remicade and Simponi

ARIA" is immaterial. Opp'n 27 (MA-5). Stripped of the legal conclusion that Janssen's conduct amounted to inducement, Relator merely asserts that Janssen was educating physicians on IOI in hopes that physicians would administer Remicade in-office—a proposition clearly established by public disclosures. *See, e.g.* McHugh Decl., Ex. J, at 10 ("*To ensure physicians would administer Remicade in their offices*," Centocor "arrange[d] education for the physicians concerning the mechanics of billings and reimbursements, and respond[ed] to physician concerns about the financial risks and disincentives associated with the drug." (emphasis added)).

Relator also asserts as material her allegation that Janssen provided IOI education "for free." Opp'n 26 (MA-3). That, too, is plain from public disclosures. As Centocor executives made clear in *AWP*, the purpose of educating physicians on IOI was to "respond to physician concerns about the financial risks and disincentives associated with" IOI of Remicade, and "[t]o ensure physicians would administer Remicade in their offices." McHugh Decl., Ex. J, at 10; *see also* Hoffman Dep., Ex. B, at 11–12 (similar). No one reading that testimony would assume Centocor was *charging* physicians for that education. And in fact, it was disclosed in *AWP* that certain of the public disclosures at issue were freely available on Centocor's website. *See, e.g.*, J&J Trial Brief, Ex. F, at 6 ("The Guide . . . was distributed to physicians and posted on Centocor's web site[.]"); Hoffman Dep., Ex. B, at 19, 21 ("The financial impact worksheet on page 8 [of the Guide] was that also available at Centocor's Website at some point? Yes, I believe it was.").[13]

Relator also asserts that her allegation that the scheme persisted from October 2010 to the present is a "material addition." Opp'n 28 (MA-8). But as noted, *supra,* at 3, "there was every reason to think that" Janssen's alleged "scheme would" continue given Janssen's own public

[13] The Guide was thus also publicly disclosed "in the media." *See, e.g., U.S. ex rel. Green v. Serv. Cont. Educ. and Training Tr. Fund*, 843 F. Supp. 2d 20, 32 (D.D.C. 2012) ("The FCA does not define 'news media,' and courts that have considered the issue have construed the term to include readily accessible websites." (collecting cases)).

disclosure that it was educating physicians about IOI, *Winkelman*, 827 F.3d at 212, and in any event, Relator fails to explain why it would influence the Government's decisionmaking for it to know that Janssen was continuing to offer education it had been openly providing for years.[14]

Likewise, other of Relator's supposed additions are offered with no explanation of how they might "influence the behavior of the" Government. *Winkelman*, 327 F.3d at 201. Relator points out that public disclosures did not expressly reveal that Janssen began offering IOI education to providers "to prescribe Simponi ARIA in addition to Remicade." Opp'n 30 (MA-9). But Relator offers no reason why educating physicians about Simponi ARIA, a successor medicine to Remicade, could possibly be material to the Government in light of Janssen's open disclosure that it provided such education with respect to Remicade. Similarly, Relator states that her "[k]nowledge gained from providing the IOI support for 13 years" is material, without explaining what that knowledge actually *is* or *why* it is material. Opp'n 26 (MA-1).

Relator's other efforts to show materiality also fail. Relator asserts that she offered "[s]pecific and detailed information" suggesting "that Janssen knew that it was unlawful to provide the services to select physician practices for free." Opp'n 27 (MA-6). As an initial matter, Relator far overstates her additions on the question of scienter. *See* Order, ECF. No. 75, at 23–25 (some of Relator's scienter allegations are "conclusory," "other[s]" plausibly allege "that at least some of defendant's employees" had scienter). Furthermore, Janssen's scienter was alleged in the FCA claims in both *Heineman* and *Greer*.[15] In any event, Relator's allegations of scienter are

[14] Relator's citation to *U.S. ex. rel. Fernandez v. Freedom Health, Inc.*, No. 18-cv-1959, 2021 WL 2954415 (M.D. Fla. May 26, 2021), is distinguishable. That case held only that a relator was an original source where he alleged fraud beyond the period covered by a previous settlement.

[15] *See, e.g.*, *Heineman* Compl., Ex. N, at ¶ 61 ("The defendants knowingly presented or caused to be presented a false or fraudulent claim for payment upon the United States Government" by "[i]mproperly providing financial compensation to providers for performing 'educational' presentations designed to increase the provider's practice and increase the use of Remicade" and

immaterial given that "the public disclosures made it pellucid that" Janssen "deliberately" offered education to physicians about IOI of Remicade. *Winkelman*, 827 F.3d at 213.

Finally, Relator alleges that she is an original source based on information she obtained *in this litigation*. Opp'n 30 (MA-10). But the original source provision requires a relator's allegations to have been provided "to the Government *before filing an action under this section*." 31 U.S.C. § 3730(e)(4)(B)(2) (emphasis added). Information obtained after filing this action in 2016 cannot save Relator from her failure to materially add to the disclosures in *AWP*, *Heineman*, and *Greer*, and she should not be permitted to amend her SAC to cure these deficiencies.[16]

CONCLUSION

For the foregoing reasons, Janssen respectfully requests that the Court enter judgment on the pleadings to Janssen.

"[i]mproperly using peer-to-peer reviews and utilizing consultants as a marketing opportunity to induce increased use of Remicade."); *Greer* Compl., Ex. O, at ¶ 93 ("Centocor did knowingly, willfully, and unlawfully cause false statements to be made or used by others to have false and fraudulent claims paid by" government programs, "as the result of an illegal inducement by which Defendant Centocor usurped or supplanted the independent medical judgment of physicians.").

[16] Neither *U.S. ex rel. Howard v. KBR, Inc.*, 471 F. Supp. 3d 846 (C.D. Ill. 2020), nor *U.S. ex rel. Galmines v. Novartis Pharms. Corp.*, 88 F. Supp. 3d 447 (E.D. Pa. 2015), support granting Relator leave to amend. *Howard* did not concern amendment at all, but instead a conclusion that certain documents turned over in discovery confirmed that the relator's own additions were material. The relator in *Galmines* was allowed to amend to allege fraud for an additional time period, but only following an earlier ruling that he was an original source with respect to the underlying scheme.

Dated: April 21, 2023

Respectfully submitted,

/s/ Ethan M. Posner

Ethan M. Posner (admitted *pro hac vice*)
Matthew F. Dunn (admitted *pro hac vice*)
Jason C. Raofield (BBO No. 641744)
Kristin M. Cobb (admitted *pro hac vice*)
Nicholas O. Pastan (admitted *pro hac vice*)
Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000
eposner@cov.com
mdunn@cov.com
jraofield@cov.com
kcobb@cov.com
npastan@cov.com

Attorneys for Defendant Janssen Biotech, Inc.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on this 21st day of April, 2023.

/s/ Ethan M. Posner
Ethan M. Posner (admitted *pro hac vice*)